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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,363	10/05/2004	Richard A. Fishel	SCHN-0033	9543

7590  
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04/10/2007

EXAMINER
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VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/510,363

Applicant(s)

FISHEL ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-132 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-132 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-35, and 74, 131, 132 drawn to a method of screening for a compound which induces a DNA repair pathway of a cell comprising contacting at least one component of a DNA repair pathway with a non-circularized retroviral cDNA in the presence of a test compound, and determining the amount of retroviral cDNA circularization.

Group II, claim(s) 36, 37 drawn to a compound that induces a DNA repair pathway of a cell or a pharmaceutical composition comprising said compound.

Group III, claim(s) 38-45, drawn to a method of inducing a DNA repair pathway of a cell comprising administering at least one compound that induces DNA repair.

Group IV, claim(s) 46-47, 67-73, 110-111, 129, 130, drawn to a kit for identifying a compound that induces a DNA repair pathway comprising a retrovirus or retroviral vector having a marker gene that is expressed upon retroviral cDNA circularization.

Group V, claim(s) 49-56, 75, drawn to a method of identifying a compound that inhibits retroviral cDNA integration into a host genome.

Group VI, claim(s) 57 and 58, drawn to a compound that inhibits retroviral cDNA integration into a host cell genome, and a pharmaceutical composition comprising said compound.

Group VII, claim(s) 59-65, drawn to a method of inhibiting retroviral cDNA integration into a host cell genome by administering a compound which inhibits retroviral cDNA integration into a host genome.

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Group VIII, claims 76-101, 131 and drawn to a method of identifying a compound that inhibits a DNA repair pathway of a cell.

Group IX, claim(s) 102-103, drawn to a compound that inhibits a DNA repair pathway of a cell, and a pharmaceutical composition thereof.

Group X, claim(s) 104-109, drawn to a method of inhibiting a DNA repair pathway of a cell comprising administering at least one compound.

Group XI, claim(s) 113-120, 132, drawn to a method of identifying a compound that increases retroviral cDNA integration into a host genome.

Group XII, claim(s) 121, 122, drawn to a compound, and pharmaceutical composition comprising said compound that increases the efficiency of gene delivery in a gene therapy.

Group XIII, claim(s) 123-127, drawn to a method of increasing retroviral cDNA integration into a host cell genome by administering a compound to a cell or patient.

Claims 48, 66, 112, 128 are drawn to non-statutory subject matter, since they are "use" claims. The subject matter intended by these claims cannot be determined and therefore they are not included in the restriction groups.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups I, III, V, VII, VIII, X, XI, XII are biologically and functionally different and distinct from each other and thus one does not render the other obvious.

The methods of Groups I, III, V, VII, VIII, X, XI, XII comprise steps which are not required for or present in the methods of the other groups: determining whether the amount of retroviral cDNA circularization is increased in the presence of a test compound and contacting at least one component of a DNA repair pathway with a non-circularized retroviral cDNA in the absence and presence of a test compound (I);

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administering a compound that increases retroviral cDNA circularization (III); contacting a cell with a non-circularized retroviral cDNA in the presence of a test compound to determine if said compound inhibits retroviral cDNA integration into a host genome (V); administering a compound that inhibits retroviral cDNA integration into a host cell genome (VII); contacting a component of a DNA repair pathway with a non-circularized retroviral cDNA in the presence of a test compound to determine its affect on inhibiting DNA repair pathway, and determining whether the amount of retroviral cDNA circularization is decreased in the presence of a test compound (VIII); administering a compound that inhibits DNA repair (X); contacting cells with a non-circularized retroviral cDNA with a test compound to determine its affect on increasing retroviral cDNA integration into a host genome (XI); and administering a compound that increases retroviral cDNA integration into a host cell genome (XIII). The end result of the methods are different: isolation of a compound that induces DNA repair pathway of a cell (I); a cell which has increased DNA repair (III); isolation of a compound that inhibits retroviral cDNA integration (V); a host cell which has inhibited retroviral cDNA integration (VII); isolation of a compound which inhibits DNA repair (VIII); a cell that has inhibited DNA repair (X); identification of a compound that increases retroviral cDNA integration into a host genome (XI), and a host cell which has increased retroviral cDNA integration into the genome (XIII). Thus, the operation, function and effects of these different methods are different and distinct from each other, and therefore there is no special technical feature in common.

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Inventions of Group IV and Groups I, V, VIII, XI, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in each of the different processes of use set forth in Groups I, V, VIII, XI and XIII, and therefore the groups do not share a special technical feature.

Inventions of Groups II, VI, IX, and XII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not share a special technical feature since they are drawn to distinct compounds having different affects, and having unknown and distinct structures. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Except for the specific relationships described above, the invention of Groups I, III, V, VII, VIII, X, XI, XIII and II, IV, VI, IX, XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04,

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MPEP 808.01). In the instant case the different products of Groups II, IV, VI, IX, XII are not used in or made by the methods of Groups I, III, V, VII, VIII, X, XI, XIII.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV  
4/2/07

  
NANCY VOGEL  
PRIMARY EXAMINER